Enforcement Report - Week of February 24, 2021

Class I Drugs Event

Event ID:
86078

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/12/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Liq-E S.A. De C.V.
Puerto Tampico 345
San Nicolas De Los Georgia Mexico

Distribution Pattern:
Distributed Nationwide in the United States and Mexico.

Associated Products

Product Description:
OPTIMUS LUBRICANTS Instant Hand Sanitizer, (ethyl alcohol 70%) 8.5 Fl. Oz. (250 mL) bottle, Made in Mexico, Liq-E, S.A. DE C.V., Puerto Tampico No. 345 Col. La Fe San Nicolas de Los Garza, Nuevo Leon, Mexico. C.P. 66477. UPC # 7 501799 115621

Product Quantity:
12,201 bottles

Reason for Recall:
Chemical Contamination: Products contain methanol and were below the label claim for ethanol content

Recall Number:
D-0253-2021

Code Information:
Lot # (L)20-02, exp. date 05/2022

Product Description:
OPTIMUS LUBRICANTS Instant Hand Sanitizer, (alcohol 70% v/v) 55 Gal (208 L) drum, Made in Mexico, Liq-E, S.A. DE C.V., Puerto Tampico No. 345 Col.. La Fe San Nicolas de Los Garza, Nuevo Leon, Mexico. C.P. 66477.UPC # 7 501799 118998

Product Quantity:
575 drums

Reason for Recall:
Chemical Contamination: Products contain methanol and were below the label claim for ethanol content

Recall Number:
D-0254-2021

Code Information:
Lot # L-1160, L-2160, L-3160, L-1180, L-2180, L-2190, Exp. 05/2022; L-1200, L-2200, L-3200, L-4200, L-5200, L-1210 and L-2210, Exp. date 06/2022

Product Description:
OPTIMUS LUBRICANTS Instant Hand Sanitizer, (ethyl alcohol 70%) 1 Gal (3.78 L) bottle, Made in Mexico, Liq-E, S.A. DE C.V., Puerto Tampico No. 345 Col. La Fe San Nicolas de Los Garza, Nuevo Leon, Mexico. C.P. 66477; NDC: XXXXX-378-04, UPC # 7 501799 118837

Product Quantity:
6,597 gallons

Reason for Recall:
Chemical Contamination: Products contain methanol and were below the label claim for ethanol content

Recall Number:
D-0255-2021

Code Information:
Lot # (L) 20-03, exp. date 05/22

Product Description:
OPTIMUS LUBRICANTS Instant Hand Sanitizer, (alcohol 70% v/v) 275 Gal (1040 L) tank with spout dispenser, Made in Mexico, Liq-E, S.A. DE C.V., Puerto Tampico No. 345 Col. La Fe San Nicolas de Los Garza, Nuevo Leon, Mexico. C.P. 66477.; UPC # 7 501799 118981

Product Quantity:
1 tank

Reason for Recall:
Chemical Contamination: Products contain methanol and were below the label claim for ethanol content

Recall Number:
D-0256-2021

Code Information:
Lot # (L) 5200, exp. date 05/2022

Class II Drugs Event

Event ID:
87214

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/18/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Cephalexin for Oral Suspension, USP 250 mg per 5 mL, 100 ml (when mixed) Rx Only, Manufactured by: Alkem Laboratories, Ltd, Mumbai -400 013 INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-545-88

Product Quantity:
14,205 100 mL bottles

Reason for Recall:
CGMP Deviations: Individual Unidentified impurities results of the product was found at higher side of the specification limit.

Recall Number:
D-0263-2021

Code Information:
Lot # 19144841, Exp 9/2021; 20141673 Exp 4/2022.

Product Description:
Cephalexin for Oral Suspension, USP 250 mg per 5 mL 200 ml (when mixed) Rx Only, Manufactured by: Alkem Laboratories, Ltd, Mumbai -400 013 INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-545-68

Product Quantity:
23,436 200 mL bottles

Reason for Recall:
CGMP Deviations: Individual Unidentified impurities results of the product was found at higher side of the specification limit.

Recall Number:
D-0264-2021

Code Information:
Lot #: 19141869, 19141870, EXP 3/2021; 19142762, EXP 5/2021; 19143826, 19143923,19143941, 19143954 EXP 7/2021

Class II Drugs Event

Event ID:
87257

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/12/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
DLC Laboratories, Inc
7008 Marcelle St
Paramount CA United States

Distribution Pattern:
Distributed Nationwide and to the following foreign countries: Canada, Cambodia, Germany, and United Kingdom.

Associated Products

Product Description:
Sulfur Ointment 10%, Pomada de Azufre, 2.6 OZ (73.7g) jar; Manufactured by/ Fabricado por: De La Cruz Products, A Division of DLC Laboratories, Inc. Paramount, CA 9023 USA; UPC 024286150426

Product Quantity:
86,297 jars

Reason for Recall:
Labeling: Label Mix-Up. THe English label with Drug Facts panel for Camphor was incorrectly placed on product.

Recall Number:
D-0257-2021

Code Information:
Lot # 5084, Exp 05/23; 5130, Exp 07/23; 5132, Exp 07/23; 5160, Exp 08/23.

Class II Drugs Event

Event ID:
87268

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/04/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/16/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wilshire Pharmaceuticals Inc
6 Concourse Pkwy NE
Atlanta GA United States

Distribution Pattern:
FL, TX

Associated Products

Product Description:
Meclizine HCl Tablets, USP, 12.5 mg, 100 Tablets bottles, Rx Only, Mfd. for: Wilshire Pharmaceuticals, Inc., Atlanta, GA 30328, Product of India, NDC 52536-129-01

Product Quantity:
2112 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0258-2021

Code Information:
Lot #: 18030318, Exp 03/2021

Product Description:
Meclizine HCl Tablets, USP, 25 mg, 100 Tablets bottles, Rx Only, Mfd. for: Wilshire Pharmaceuticals, Inc., Atlanta, GA 30328, Product of India, NDC 52536-133-01

Product Quantity:
35928 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0259-2021

Code Information:
Lot #: 18030329, 18030330, 18030331, Exp 03/2021.

Class III Drugs Event

Event ID:
87256

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/17/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akebia Therapeutics dba Keryx Biopharmaceutials, Inc
245 1st St
Cambridge MA United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Auryxia (ferric citrate) tablets, 210 mg*, 200 tablets bottle, RX ONLY, Manufactured for and distributed by: KERYX BIOPHARMACEUTICALS, INC., 245 First Street, Suite 1400, Cambridge, MA 02142, USA, NDC 59922-0631-01.

Product Quantity:
17,664 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0260-2021

Code Information:
Lots #: CDKSN, CDPPH, Exp January 2022; Lot #: CDPPK, Exp February 2022.